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10/550,624	07/17/2006	Koichi Sugita	024918-0124	4611

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EXAMINER	
DESAI, ANAND U	
ART UNIT	PAPER NUMBER
1656	
MAIL DATE	DELIVERY MODE
10/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,624	SUGITA ET AL.	
	Examiner	Art Unit	
	ANAND U. DESAI, Ph.D.	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *1-18 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-21 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 September 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20050926;20080630*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group V, claims 19-21 and 23, drawn to a GLP-1 derivative that consists of the amino acid sequence shown in SEQ ID NO: 6 in the reply filed on February 29, 2008 and June 30, 2008 is acknowledged. The traversal is on the ground(s) that groups III-V form a single general inventive concept, and thus should be examined together. Applicant's state the common special technical feature is that the groups describe GLP-1 derivatves that are trypsin-resistant. Applicant's further state that groups III-V should be an election of species. Applicants additionally traverse the restriction requirement on the grounds that the search and examination of groups III-V is not unduly burdensome. This is not found persuasive because the search of SEQ ID NO: 6 will not result in the search and examination of different structural compositions with different SEQ ID NOs. Furthermore, the sequences are not obvious variants of each other.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-18 and 22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on February 29, 2008 and June 30, 2008.

3. Claims 19-21 and 23, drawn to GLP-1 derivatives, including SEQ ID NO: 6 are currently under examination.

Priority

4. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

5. Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a certified English translation of the foreign application must be submitted in reply to this action. 37 CFR 41.154(b) and 41.202(e).

Failure to provide a certified translation may result in no benefit being accorded for the non-English application.

6. The priority date is February 28, 2003.

Information Disclosure Statement

7. The information disclosure statements (IDSs) submitted on September 26, 2005 and June 30, 2008 are being considered by the examiner. The NPL documents cited on the September 26, 2005 IDS have not been considered, because the references have not been provided. The WO document was available and was considered. A file copy of WO 01/55213 will be placed in the instant application.

Drawings

8. The drawings are objected to because in Figure 5 there is no y-axis label. In Figure 9 the x-axis is not labeled at the bottom. Figure 13 does not have a concentration for the first bar in the figure. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet,

even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

9. The disclosure is objected to because of the following informalities:

10. The disclosure has improper grammar throughout and is difficult to read. Suggest fixing the grammar to conform to English language. It appears to comprise translations of a foreign document. There are multiple sentences throughout the disclosure that are difficult to comprehend. In addition, what is a skim when describing the figures?

Appropriate correction is required.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection

is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 19-21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 7,291,594 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are of overlapping scope. The structure of SEQ ID NO: 19 of the issued patent is encompassed by the structure being claimed in the instant application pending claims, wherein the modification can comprise one or more substitutions, insertions, and/or deletions.

Claim Rejections - 35 USC § 112

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 19-21, and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15. Claim 19 recites the limitation "the peptide" in the second to last line. There is insufficient antecedent basis for this limitation in the claim. It is unclear if the peptide is referring to a GLP-1 peptide or a GLP-1 derivative that has a peptide. Is it intended to be "the GLP-1 derivative"?

16. Claim 19 recites the limitation "the physiological activity thereof" in the last line of the claim. There is insufficient antecedent basis for this limitation in the claim. What physiological activity is being referred to?

17. Claims 20, 21, and 23 are rejected for depending on a rejected base claim and failing to cure the indefiniteness.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description

18. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

19. Claims 19-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are rejected under 35 U.S.C. 112, first paragraph, Written Description, because the disclosure does not direct one of ordinary skill in the art to the genus of GLP-1 derivatives with any modification of the peptide as currently encompassed by claim 19. The

claims are also rejected for failing to describe a genus of GLP-1 activities with the genus of modified peptides. Claims 20 and 21 are rejected for failing to further describe a modification.

The Guidelines for Examination of Patent Applications under the 35 U.S.C. 112, Paragraph 1, "Written Description" Requirement, published at Federal Register, Vol. 66, No. 4, pp. 1099-1111 outline the method of analysis of claims to determine whether adequate written description is present. The first step is to determine what the claim as a whole covers, i.e., discussion of the full scope of the claim. Second, the application should be fully reviewed to understand how applicant provides support for the claimed invention including each element and/or step, i.e., compare the scope of the claim with the scope of the description. Third, determine whether the applicant was in possession of the claimed invention as a whole at the time of filing. This should include the following considerations: (1) actual reduction to practice, (2) disclosure of drawings or structural chemical formulas, (3) sufficient relevant identifying characteristics such as complete structure, partial structure, physical and/or chemical properties and functional characteristics when coupled with a known or disclosed correlation between function and structure, (4) method of making the claimed invention, (5) level of skill and knowledge in the art and (6) predictability of the art. For each claim drawn to a single embodiment or species, each of these factors is to be considered with regard to that embodiment or species. For each claim drawn to a genus, each of these factors is to be considered to determine whether there is disclosure of a representative number of species that would lead one skilled in the art to conclude that applicant was in possession of the claimed invention. Where skill and knowledge in the art is high adequate written description would require fewer species to

be disclosed than in an art where little is known; further, more species would need to be disclosed to provide adequate written description for a highly variable genus.

First, what do the claims as a whole cover? Claims 19-21 are drawn to a GLP-1 derivative having a GLP-1 activity (one of many possible), comprising a substitution of lysine with asparagine or aspartic acid at the 34th position and a substitution of lysine with glutamine at the 26th position in a GLP-1 peptide having an amino acid sequence of GLP-1 (7-36) or GLP-1 (7-36) with a modification of the peptide which does not substantially alter the physiological activity thereof.

Second, how does the scope of the claims compare to the scope of the disclosure?

The disclosure describes the production of (Ser^{8})–GLP-1 (7-36 amide), (Gly^{8})-GLP-1 (7-36 amide), (Gln^{26}, Asn^{34})–GLP-1 (7-36 amide), (Ser^{8}, Gln^{26}, Asp^{34})–GLP-1 (7-36 amide), and (Ser^{8}, Gln^{26}, Asn^{34})–GLP-1 (7-36 amide) having trypsin and dipeptidylpeptidase IV resistance. Although, the disclosure does not describe a representative genus of modified peptides with various physiological activities as currently encompassed by the claims.

What is the level of predictability of the art?

The level of predictability in this art is very low since, until the modification is examined, there is no information upon which to base a prediction of what molecule might be suitable as a GLP-1 derivative and what associated function is attributed to the modification.

Thus, having analyzed the claims with regard to the Written Description guidelines, it is clear that the specification does not disclose a representative number of species which would lead one skilled in the art to conclude that applicant was in possession of the claimed invention of a genus of modifications.

Claim Rejections - 35 USC § 102

20. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

21. Claims 19-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Dong (U.S. Patent 6,903,186 B1)

22. Dong discloses peptide analogs of GLP-1 and pharmaceutically acceptable salt thereof. The structure disclosed by Dong encompasses a GLP-1 (7-36) that has a C-terminal amide (see claim 1). The pending claims are drawn to modified GLP-1 derivatives, which encompass at

least one or more substitution, insertions, and/or deletions. Dong's peptide analogs encompass such a GLP-1 derivative.

23. Claims 19-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Dong (U.S. Patent 7,268,213 B1)

24. Dong discloses peptide analogs of GLP-1 (see Abstract). The structure disclosed by Dong encompasses a GLP-1 (7-36) that has a C-terminal amide (see claim 12). The pending claims are drawn to modified GLP-1 derivatives, which encompass at least one or more substitution, insertions, and/or deletions. Dong's peptide analogs encompass such a GLP-1 derivative.

25. Claims 19-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Dong (U.S. Patent 7,368,427 B1)

26. Dong discloses peptide analogs of GLP-1 (see Abstract). The structure disclosed by Dong encompasses a GLP-1 (7-35) that has a C-terminal amide (see claim 1). The pending claims are drawn to modified GLP-1 derivatives, which encompass at least one or more substitution, insertions, and/or deletions. Dong's peptide analogs encompass such a GLP-1 derivative.

27. Claims 19-21 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Hayashi et al. (JP 2002-299283; October 11, 2002).

28. Hayashi et al. disclose a composition that has 100 % identity with the sequence disclosed as SEQ ID NO: 6 (see page 4, paragraphs 1 and 2).

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Conclusion

29. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANAND U. DESAI, Ph.D. whose telephone number is (571)272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on (517) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

October 20, 2008
/ANAND U DESAI, Ph.D./
Examiner, Art Unit 1656